***United States Court of Appeals***

***for the Second Circuit***

# APPENDIX

ORIGINAL
WITH PROOF
OF SERVICE

# 75-7122

## UNITED STATES COURT OF APPEALS

*for the*

## SECOND CIRCUIT

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Appellants,

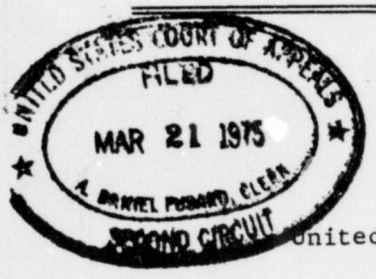
v

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education, and Welfare of the United States of America,

Appellees.

ON APPEAL FROM AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

APPENDIX

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Attorneys for Appellants
232 West End Avenue, New York, N. Y. 10023

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Municipal Building, New York, N. Y.

(4641A)

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PAGINATION AS IN ORIGINAL COPY

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CIVIL DOCKET

UNITED STATES DISTRICT COURT

Jury demand date:

D. C. Form No. 106 Rev.

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ATTORNEYS

For plaintiff:
ROTHBLATT, ROTHBLATT, SEIJAS & PESKIN
232 West End Avenue
N.Y.C. N.Y. 10023
787- 7001

SOUTHERN DISTRICT OF NEW YORK

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY ROMIS, and STANLEY WEINRIB on behalf of themselves, and all other persons similarly situated,
Plaintiffs,

v.

OSEPH CIMINO, M.D. individually and as ommissioner of the Department of Health f the City of New York; the Department f Health of the City of New York; the Board f Health of the City of New York; GORDON HASE, individually and as Administrator f the Health Services Administration, and he Health Services Administration, HOLLIS S. NGRAHAM, M.D. individually and as Commissioner the Department of Health of the State of w York and the Department of Health of the tate of New York; the Public Health Council the Department of Health of the State of York; CASPER WEINBERGER, individually and Secretary of the Department of Health, ucation, and Welfare of the United States America and the Department of Health, ucation and Welfare of the United States of erica.

Defendants.

For defendant:
U.S.Attorney
Norman Redlich
Coporation Counsel
Municipal Building, N.Y. 10007
Deft's Cimino & Chase.

Louis J. Lefkowitz
Atty. General of the State of
2 World Trade Center, N.Y.

| STATISTICAL RECORD | COSTS | | DATE | NAME OR RECEIPT NO. | REC. | DISB. |
|---|---|---|---|---|---|---|
| J.S. 5 mailed X | Clerk | | 1/4/73 | Rothblatt | 15 — | |
| | | | 5/24/73 | U.S.M. | — — | 15 — |
| J.S. 6 mailed ✓ | Marshal | | 5/24/74 | Roth Blatt filing | 5 — | 5 — |
| Basis of Action: CIVIL RIGHTS. | Docket fee | | | | | |
| | Witness fees | | | | | |
| Action arose at: | Depositions | | | | | |

DANIEL FRIEDLANDER, ETC. VS J. CIMINO, M.D. ET-AL

73 CIV. 22

| DATE | PROCEEDINGS |
|---|---|
| May22-73 | Filed Complaint. Issued Summons. |
| Jun4-73 | Filed summons and entered marshal's return served on:<br>Joseph Ciniro by Mack Weinberger on 5-25-73,<br>Board of Health, City of New York by Mark Weinberger on 5-25-73,<br>Gordan Chase by H. Stults on 5-25-73,<br>Hollis S. Ingraham by Donald MacHarg on 5-24-73 &<br>Public Health Council by Donald MacHarg on 5-24-73. |
| Jun4-73 | Filed summons and entered marshal's return served on:<br>Mr. Casper Weinberger by certified mail #4594859 on 5-25-73<br>& Dept of Health, Education & Welfare by certified mail on<br>#594860 on 5-25-73. |
| Jun 14,73 | Filed Stip and order extending defts. Cimino and Chase time to answer until July 25,73. SO ORDERED. BONSAL, J. |
| Jul 16-73 | Filed Stip & Order extending defts Ingraham and Public Health Council of the Dept. of Health of State of NY to 7/24/73.BONSAL,J. |
| Jul 20-73 | Filed Defts Affdvt by David W.Fisher & Notice of Motion ret.7/23/73,10:00 A.M., Room 1105 re:enlargement of time to answer complaint to 9/28/73 |
| Jul 20-73 | Filed Defts. Ingraham & the NY State Public Health Notice of Motion ret.7/23/73 re:order enlarging the state defts'time to answer complaint. |
| Jul23-73 | Filed Govt's notice of motion and affdvt re: order enlarging defts' time to move with respect to the complaint herein from 7/29/73 to 9/29/73. |
| Jul23-73 | Filed MEMO-END. on motion dtd this date. Motion granted. No opposition defts may move with respect to complaint on or before 9-29-73 BONSAL,J. (mn) |
| Jul 24-73 | Filed Memo End. on motion dated 7/20/73.Motion granted.No opposition .Defts may move with respect to complaint on or before 9/29/73.BONSAL,J.(mn) |
| Jul 24-73 | Filed Memo End. on Notice of Motion dated 7/20/73.Motion granted.No opposition. Defts may move with respect to complaint on or before 9/29/73.BONSAL,J(mn) |
| Sep 26-73 | Filed Stip & Order extending time for defts. Joseph Cimino,Dept of Health of City of NY,Board of Health of City of NY&Gordon Chase to answer complaint to 10/5/73.BONSAL,J. |
| Sep 27-73 | Filed Defts.Casper Weinberger&Dept of HE&W's ANSWER to Complaint |
| Oct.12-73 | Filed stip & order that time of State Deft's to answer is ext. to. 12-12-73. Bonsal,J. |
| Oct.19-73 | Filed ANSWER to complaint by deft's Cimino,M.D.,Gordon,The Dept.of, Health & Board of Health & Health Services Admin. |
| Oct.12-73 | Filed ANSWER to complaint by deft's. |
| Dec.26-73 | Filed stip & order that deposition of Hollis S. Ingraham shall be, noticed for 1-30-74. Bonsal,J. |
| Dec.26-73 | Filed stip & order that depositions of deft. J.Cimeno & G.Chase ret 12-20-73 adj. to 1-30-74. |
| Dec.26-73 | Filed pltff's notice to take deposition of C.Weinberger.(filed 12-13-73) |
| Dec.26-73 | Filed pltff's notice to take deposition of Gordon Chase " " " " |
| Dec.26-73 | Filed pltff's notice to take deposition of J.Cimeno . " " " " |
| Dec.26-73 | Filed pltff's notice to take deposition of H.S. Ingraham. " " " " |
| Jan.15-74 | Filed state Deft's affidavit & notice of motion granting judgment, ret.1-28-74. |
| Jan.15 74 | Filed State deft's memorandum of law in support of motion ret.1-28-74. |
| Jan.28-74 | Filed stip & order that pltff's time to answer deft's motion for summary judg. is ext. to 2-18 74. Bonsal,J. |



Cont'd on page #2

JUDGE BONSAL

| DATE | FILINGS—PROCEEDINGS |
|---|---|
| Feb.25-74 | Filed deft's affidavit & notice of motion(Municipal deft's) summary judgment ret.3-4-74. |
| Feb.25-74 | Filed deft's (Municipal deft's) memorandum of law in support of motion ret.3-4-74. |
| Feb.25 74 | Filed Deft's(Municipal Deft's) statement under rule 9G. |
| Jul.2-74 | Filed affidavit of Rose L. Berman in opposition to deft's, motion for summary judgment. |
| Jul.2-74 | Filed pltff's reply to rule 9(g) statement. |
| Jul.2-74 | Filed pltff's memorandum of law in opposition to motion for, summary judgment. |
| Dec.3-74 | Filed Memorandum-Decision #41508: The State & City deft's motions for judgment on the pleadings are granted. Settle order on notice. Bonsal,J. m/n |
| Dec.27-74 | Filed pltff's notice of appeal to the USCA from order entered 12-3-74. Mailed copies to US.Atty, Louis Lefkowitz & Adrian P. Burke,Corporation Counsel. |
| Jan.10-75 | Filed Notice of settlement of order & judgment: Ordered that the State & City deft's motions for judgment on the pleadings are granted. Ordered that the complaint is dismissed Bonsal,J. Judgment Ent. Clerk. m/n Ent. 1-15-75 |
| Jan.23-75 | Filed pltff's notice of appeal to the USCA from order dismissing action dated 1-10-75. Mailed copies to U.S. atty., Louis J. Lefkowitz & Norman Redlich. |
| 2-11-75 | Filed certification of record on appeals to the USCA for original record on 2-11-75 |

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D. individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D. individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America.

Defendants.

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COMPLAINT

73 Civ. 2276 (DBB)

The plaintiffs, by their attorneys, ROTHBLATT, ROTHBLATT, SEIJAS & PESKIN, on behalf of themselves and all other non-physician, self-employed clinical laboratory directors in the City of New York similarly situated allege:

FOR A FIRST, SEPARATE, AND COMPLETE CAUSE OF ACTION. FOR DAMAGES, TO REDRESS PLAINTIFFS FOR THE DEPRIVATION, BY DEFENDANTS UNDER COLOR OF STATE LAW, OF RIGHTS, PRIVILEGES, AND IMMUNITIES GUARANTEED BY THE CONSTITUTION AND THE LAWS OF THE UNITED STATES OF AMERICA.

COMPLAINT

1. This is a class action brought on behalf of all the non-physician, self-employed clinical laboratory directors in the City and State of New York against the Commissioner of the Department of Health of the City of New York, the Board of Health of the City of New York, the Administrator of the Health Services Administration and the Health Services Administration of the City of New York, the Commissioner of the State Department of Health and the Department of Health of the State of New York, the Public Health Council of the State Department of Health, the Secretary of the Department of Health, Education and Welfare of the United States and the United States Department of Health, Education and Welfare.

2. The above-named plaintiffs sue on behalf of themselves and all other non-physician, self-employed clinical laboratory directors in the City and State of New York. The class is so numerous that joinder of all members is impracticable. There are questions of law and fact common to the class. The plaintiffs will fairly and adequately protect the interests of the class. The common questions of law and fact predominate over any questions affecting only individual members, and a class action is superior to any other available methods for the fair and efficient adjudication of the controversy.

3. Each of the plaintiffs named herein is a non-physician self-employed clinical laboratory director in the State of New York properly licensed to practice their profession by the

Department of Health of the City of New York or Health Department of the State of New York and is fully authorized to direct a Clinical Laboratory in the City or State of New York.

4. At all the times hereinafter mentioned, the defendants, the Board of Health, the Department of Health and the Health Services Administration were and still are municipal agencies created under the provisions contained in the Charter and Administrative Code of the City of New York.

5. Defendant, the Department of Health of the State of New York is an agency properly created under the laws of the State of New York. The Public Health Council is an agency of the State Department of Health.

6. Dr. Joseph Cimino is the Commissioner of the Department of Health of the City of New York.

7. Gordon Chase is the Administrator of the Health Services Administration of which the Department of Health is a subdivision.

8. Dr. Hollis Ingraham is the Commissioner of the New York State Department of Health.

9. Caspar Weinberger is the Secretary of the Department of Health, Education and Welfare.

10. The jurisdiction of this Court is invoked pursuant to the provisions of Title 28, United States Code, 1343, this being a suit in law and equity authorized by Title 42, United States Code, Section 1981, 1983, 1985, 1986, and 1988, to redress

the deprivation under color of state law, status, ordinance, regulation or custom of rights, privileges, and immunities secured by the Constitution and laws of the United States or by any Act of Congress providing for equal rights for citizens. The rights here sought to be redressed are rights guaranteed by the Fifth Amendment, the Thirteenth Amendment, and due process and equal protection clauses of the Fourteenth Amendment to the Constitution of the United States and Title 42, U.S. Code, Section 1981.

11. The New York City Board and Department of Health and the New York State Public Health Council and the State Department of Health have pursuant to legislative authority promulgated regulations requiring performance or proficiency testing, to allegedly, measure the accuracy of the testing and operation of the plaintiffs' clinical laboratories.

12. The Board of Health and the Departments of Health of the City and State of New York have been and continue to require plaintiffs to use their equipment, materials, reagents, etc. to perform tests on faulty and ill-prepared artificial specimens submitted by the defendants. Plaintiffs in New York City have been supplied with all reagents for prothrombin time tests. Recently defendant Health Department of the City of New York demanded that plaintiffs use their own reagents at great expense to themselves without any recompense by defendant, and if a laboratory does not comply with this they cannot be certified for medicare for this test.

13. Pursuant to the aforesaid the defendant Department of Health of the City or State of New York, from time to time give specimens or artificial specimens to plaintiffs ostensibly for "proficiency" testing of said plaintiffs.

14. The plaintiffs are required to test these "specimens" as they would actual specimens delivered to them in the course of their laboratory operation.

15. The specimens delivered to the plaintiffs by defendants are faked or artificial specimens incapable of accurate testing including poor, stained, unreadable slides.

16. Plaintiffs are required to expend great and unnecessary amounts of time and labor and to use their own equipment, materials, reagents, etc. to perform tests on faulty and ill-prepared artificial specimens allegedly to test the laboratories' accuracy and proficiency.

17. These expenditures result solely from the negligence and arbitrariness of the State and City Departments of Health and their affiliated boards and agencies.

18. Plaintiffs are required by law to conduct said performance tests at risk of losing their licenses to practice their professions.

19. This action by defendants is a seizure of property in the form of labor and materials without compensation under color of state law and in violation of due process of law and the Thirteenth Amendment to the United States Constitution.

20. By reason of the aforesaid plaintiffs have been damaged in the amount of $3,000,000.00.

FOR A SECOND SEPARATE, AND COMPLETE CAUSE OF ACTION FOR A PERMANENT INJUNCTION, PURSUANT TO 42 U.S.C. 1983 TO ENJOIN THE DEPRIVATION UNDER COLOR OF STATE LAW OF RIGHTS, PRIVILEGES, AND IMMUNITIES GUARANTEED BY THE CONSTITUTION AND THE LAWS OF THE UNITED STATES OF AMERICA.

21. Plaintiffs repeat and reallege each and every allegation contained in paragraph 1-20 herein inclusive as if the same were set forth here at length.

22. Plaintiffs further assert and claim that they have no adequate remedy at law in that failure to perform these tests as directed by the Health Department will result in loss of plaintiffs' licenses as clinical laboratory directors which will irreparably harm them.

FOR A THIRD, SEPARATE AND COMPLETE CAUSE OF ACTION AGAINST ALL THE DEFENDANTS FOR INJUNCTIVE RELIEF.

23. Plaintiffs repeat and reallege each and every allegation contained in paragraph 1-22 of the complaint with the same force and effect as if set forth here at length.

24. Practicing physicians, osteopaths, dentists and podiatrists are exempted by Article 5, Title V, §579 of the Public Health Law of the State of New York, §405.1301 (b) of CFR, Title 20 Chapter III, Part 405 and 42 U.S.C., 1395 (x)s Practicing physicians are exempted by New York City Health Code

§13.03 (a). These unqualified persons may do all laboratory tests themselves or through their employees in their offices for their own patients

25. These practitioners operate their laboratories without being subject to "performance" testing or Health Department inspection although there is no basis for concluding that they will properly perform these tests, know anything about testing or will maintain adequate laboratory facilities.

26. The State and City Departments of Health and their adjunct agencies permit groups of physicians to operate clinical laboratories in violation of the licensing and performance testing requirements of the applicable law.

27. The City Department of Health and its adjunct agencies permit licensed physicians to operate private clinical laboratories for the purpose of performing tests on referral from other physicians in violation of the licensing and performance testing requirements to which licensed laboratories are subjected.

28. Further, all of the above individuals and groups operating unlicensed clinical laboratories are not subject to the onerous permit and certificate of qualification fees required of the plaintiffs herein.

29. This unequal treatment is a denial of equal protection of law guaranteed by the Constitution of the United States.

30. This completely unregulated practice of the clinical laboratory profession is in clear violation of the purpose of the State licensing law as expressed in the preamble to the New York State Public Health Law, §570 of Article V, Title V.

31 This completely unregulated practice of the clinical laboratory profession constitutes a threat to the public health and welfare and causes irreparable injury and damage to the plaintiffs who do not operate on an equal footing with practicing physician (dentist, etc.) - operated laboratories.

32. Plaintiffs have no adequate remedy at law for said injury.

AS AND FOR A FOURTH SEPARATE CAUSE OF ACTION FOR A DECLARATORY JUDGMENT AGAINST THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE.

33. Plaintiff repeats and realleges each and every statement contained in paragraphs 1-32 with the same force and effect as if fully set forth herein.

34. This is a cause of action for a declaratory judgment in a case of actual controversy pursuant to 28 USC §2201, and is brought to declare the rules relating to Independent Clinical Laboratories and their qualification for medicare coverage unconstitutional and invalid as a violation of substantive due process and equal protection of the laws.

35. The Defendant, Department of Health, Education and Welfare is the Federal agency duly authorized by Congress to pro-

mulgate regulations authorizing medicare reimbursements to medicare eligible persons for monies paid for clinical laboratory tests.

36. Pursuant to its mandate the Defendant, Department of Health, Education and Welfare promulgated regulations entitled Conditions for Coverage for Services of Independent Laboratories, CFR Title 20, Chapter III, Part 405 (hereinafter referred to as Rules),

37. Title 42 U.S.C. §1395 (x) exempts physicians performing tests, either themselves or through employees, in the physicians office from the requirements of (1) licensing by State or local authorities and (2) compliance with any other regulations promulgated by the Secretary of Health Education and Welfare for the health and safety of individuals.

38. Section 405.1301 (b) of the Rules exempts physicians performing laboratory tests under certain conditions from the necessity of complying with the Rules. The Rules state:

> Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other physicians as being available primarily for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests primarily for his own patients would be exempt from the conditions, even though such laboratory does diagnostic tests on referral from other physicians.

> Diagnostic tests furnished by out-of-hospital physicians whose primary practice is directly attending patients and/or consultations, even though conducted partly through diagnostic procedures are considered physicians' services rather than clinical laboratory services. As such, the office in which these services are provided is exempt from the conditions.

39. Rules §405.1312 and Section 13.07 (a)(2) of the New York City Health Code delegates to private professional and quasi-professional organizations the authority to certify individuals as qualified laboratory directors and eligible for medicare reimbursements.

40. The Rules require that plaintiffs be licensed by and comply with the regulations of the New York State of City Health Department in order to qualify for medicare reimbursement.

41. This adoption by The Department of Health, Education and Welfare of State and Local regulations forces the plaintiffs to participate in the abusive, wasteful and unconstitutional "proficiency" testing programs of the New York State and City Health Departments and their affiliated agencies in order to qualify for medicare reimbursement.

42. The exemption given to physicians allows them to qualify for medicare reimbursement without being subjected to state or local licensing requirements, abusive "proficiency" testing programs or the other "Conditions for Coverage." (hereinbefore referred to as the Rules), as well as the onerous permit and certificate of qualification fees required of the plaintiffs herein.

43. The exemption given to physicians by 42 U.S.C. 1395 (x)s and CFR §405.1301 (b) allows them to employ unqualified persons to perform laboratory tests, whereas the plaintiffs' hiring practices are subject to strict regulations appearing in Rules 405.1313 and 405.1315.

44. The Federal, State and City statutes and regulations and the enforcement policy of the various defendant agencies charged with enforcing the laws and promulgating regulations pursuant thereto are purposefully designed to promote the private interests of pathologists and to establish a monopoly for pathologists in the clinical laboratory profession.

45. The Rules of defendant Department of Health, Education and Welfare violate substantive due process and deny equal protection of laws guaranteed by the Constitution of the United States to the Plaintiffs creating an arbitrary classification not based on relevant criteria or distinctions between the parties in that physicians and others are allowed to operate their own laboratories for their own patients and perform laboratory tests on referral from other physicians without meeting the qualifying criteria set forth in Exhibit "A", although physicians are not necessarily qualified by virtue of their M.D. academic degree alone to competently perform or direct the performance of clinical tests.

46. Plaintiffs do not have a plain, speedy, and

adequate remedy at law for this denial of equal protection and due process of law.

WHEREFORE, the plaintiffs on their own behalf and on behalf of all others similarly situated demand judgment against the defendants:

a) in the amount of $1,000,000.00 against each defendant, State, City and Federal, which is the fair value for the plaintiffs' and others similarly situated labor, materials and use of plaintiffs' equipment in testing the ill-prepared specimens submitted by the defendant Health Departments under threat of license revocation.

b) and granting the plaintiffs an injunction against the defendants enjoining them from requiring the plaintiffs to perform any more performance testing.

c) and granting judgement against the defendants requiring them to provide for the safety and welfare of the citizens of New York State and New York City by not exempting any individual or group operating a laboratory under any conditions from the requirements of the Public Health Law, and New York City Health Code and any and all other relevant regulations.

d) judgement declaring the 42 U.S.C. 1395(s)x (10) (11), Conditions for Coverage of Services of Independent Laboratories, 20 CFR Cpt. 3, Pt. 405, and Section 405.1301 (b) void and unconstitutional and enjoining the defendant the Department of Health, Education and Welfare from economically coercing the plaintiff

by continuing to require the abusive performance testing either directly or indirectly through the several states.

e) and granting the plaintiffs such other and further relief as may be just and proper, together with the costs and disbursements of this action.

DATED: New York, New York
April 23, 1973

Yours, etc.,

ROTHBLATT, ROTHBLATT,
SEIJAS & PESKIN
Attorneys for the Plaintiff
232 West End Avenue
New York, New York 10023

State of New York )
County of New York) ss:

DANIEL E. FRIEDLANDER, being duly sworn, deposes and says that deponent is one of the plaintiffs in the within action; that deponent has read the foregoing and knows the contents thereof that the same is true to deponent's own knowledge except as to the matters therein stated to be alleged on information and belief, and that as to those matters deponent believes it to be true.

DANIEL E. FRIEDLANDER

Sworn to before me
this 4 day of May
1973.

COMPLAINT

State of New York )
County of New York) ss:

ISADORE JACOBS, being duly sworn deposes and says that deponent is one of the plaintiffs in the within action; that deponent has read the foregoing and knows the contents thereof that the same is true to deponent's own knowledge except as to the matters therein stated to be alleged on information and belief, and that as to those matters deponent believes it to be true.

ISADORE JACOBS

Sworn to before me
this 23 day of April
1973.

State of New York )
County of New York) ss:

HARRY RONIS, being duly sworn deposes and says that deponent is one of the plaintiffs in the within action that deponent has read the foregoing and knows the contents thereof that the same is true to deponent's own knowledge except as to the matters therein stated to be alleged on information and belief, and that as to those matters deponent believes it to be true.

HARRY RONIS

Sworn to before me this
23 day of April 1973.

State of New York )
County of New York) ss:

STANLEY WEINREB, being duly sworn, deposes and says that deponent is one of the plaintiffs in the within action; that deponent has read the foregoing and knows the contents thereof, that the same is true to depondent's own knowledge except as to the matters therein stated to be alleged on information and belief, and that as to those matters deponent believes it to be true.

STANLEY WEINREB

Sworn to before me this
2 day of May 1973.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D. individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America.

Defendants.

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ANSWER

73 Civ. 2276 (DBB)

Defendants Joseph Cimino, M.D., Gordon Chase, The Department of Health and The Board of Health of The City of New York and The Health Services Administration, by their attorney, Norman Redlich, Corporation Counsel, for their answer to the complaint herein:

1. Defendants deny the allegations of Paragraph 2 of the complaint.

2. Defendants admit the allegations of Paragraph 3 of the complaint as applied to plaintiffs Daniel Friedlander and Harry Ronis, but defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 as applied to the other plaintiffs.

3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraphs 5, 8 and 9 of the complaint.

4. Defendants deny the allegations of Paragraph 10 of the complaint.

5. Defendants admit the allegations of Paragraph 11 of the complaint except deny the inference that the tests do not measure the accuracy of testing and operation of plaintiffs' clinical laboratories.

6. Defendants admit so much of Paragraph 12 of the complaint as alleges that the City Board and Department of Health require plaintiffs, Friedlander and Ronis, to use their own equipment, material and reagents and that they supplied plaintiffs, Friedlander and Ronis, with reagents for prothrombin time tests in 1972 and aver that the reagents were supplied solely for defendants' purpose as an experimental program, and defendants deny that they require plaintiffs to perform tests on faulty and ill-prepared artifical specimens and lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 12 of the complaint.

7. Defendants admit the allegations of Paragraph 13 of the complaint if the word "ostensibly" is deemed to be deleted therefrom.

8. Defendants deny the allegations of Paragraph 15 of the complaint.

9. Defendants deny the allegations of Paragraph 16 of the complaint except admit that plaintiffs, Friedlander and Ronis, are required to use their own equipment, materials and reagents.

10. Defendants deny the allegations of Paragraphs 17, 19 and 20 of the complaint.

11. Defendants deny the allegations of Paragraph 22.

12. Defendants admit the allegations of Paragraph 24 if the word "unqualified" is deemed deleted therefrom.

13. Defendants deny the allegations of Paragraphs 25, 26, 27, 28, 29, 30, 31 and 32 of the complaint.

14. Defendants deny the allegations of Paragraph 39 of the complaint.

15. Defendants deny so much of Paragraph 41 as alleges that the proficiency testing program of the City Health Department is abusive, wasteful and unconstitutional.

16. Defendants deny the allegations of Paragraph 44 and 46 of the complaint.

FOR A FIRST AFFIRMATIVE DEFENSE:

17. The court lacks jurisdiction over the subject matter of the complaint.

FOR A SECOND AFFIRMATIVE DEFENSE:

18. The complaint fails to state a claim under which relief can be granted.

WHEREFORE, defendants Joseph Cimino, M.D., Gordon Chase, The Department of Health and Board of Health of the City of New York, and the Health Services Administration demand judgment dismissing the complaint together with costs and disbursements.

DATED: New York, New York
October 4, 1973

NORMAN REDLICH

Corporation Counsel
Attorney for Defendants,
Joseph Cimino, M.D., Gordon
Chase, The Department and
Board of Health of The City
of New York and the Health
Services Administration

By _____
David W. Fisher
Assistant Corporation Counsel
Room 1555
Municipal Building
New York, New York 10007
(212) 566-0197

NOTICE OF MOTION

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America.

Defendants.

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NOTICE OF MOTION FOR JUDGMENT ON THE PLEADINGS, RULE 12(c), OR SUMMARY JUDGMENT, RULE 56

73 Civ. 2276 (DBB)

SIRS:

PLEASE TAKE NOTICE that the pleadings herein having been closed, the undersigned will move this Court before the Hon. Dudley B. Bonsal in Room 1505, of the U.S. Court, Foley Square, on the 18th day of February, 1974, at 10 o'clock in the forenoon of that day or as soon thereafter as the matter can be heard for

a judgment on the pleadings in favor of the defendants Joseph Cimino, Department of Health of the City of New York, Board of Health of the City of New York, Gordon Chase and the Health Services Administration, upon the ground that on the undisputed facts appearing from the pleadings, plaintiff is entitled to the judgment as a matter of law.

In the alternative, defendants Cimino, Department of Health of the City of New York, Board of Health of the City of New York, Gordon Chase and the Health Services Administration, move upon the pleadings herein and upon the affidavit of Sylvia Blatt, sworn to February 6, 1974 annexed hereto and upon all the records, files, and proceedings in this Court for summary judgment in favor of the defendants Cimino, Department of Health of the City of New York, Board of Health of the City of New York, Gordon Chase and the Health Services Administration, on the ground that there is no genuine issue as to any material fact and for such other and further relief as may be just and proper.

DATED: New York, New York
February 6, 1974

ADRIAN P. BURKE
Corporation Counsel
Attorney for Municipal Defts.
Room 1555
Municipal Building
New York, New York 10007
566-0197

RULE 9(g) STATEMENT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America.

Defendants.

STATEMENT UNDER RULE 9G

73 Civ. 2276
D.B.B.

1. The regulation of clinical laboratories is a valid exercise of the police power.

2. For the year 1972, the medicaid reimbursement for the tests performed by plaintiff Friedlander would have been $132.

3. For the year 1972, the medicaid reimbursement for the tests performed by plaintiff Ronis would have been $191.20.

4. The laboratories operated by the two named plaintiffs in the City of New York accept medicaid fees, indicating that the cost to plaintiffs Friedlander and Ronis are less than those amounts.

5. No one is required to perform proficiency tests on unsatisfactory specimens.

6. On only one occasion did plaintiff Ronis return a specimen as unsatisfactory.

7. Plaintiff Ronis was not penalized for not testing the specimen returned as unsatisfactory.

8. Plaintiff Friedlander never returned a specimen as unsatisfactory.

9. Physicians who perform tests on other than their own patients are required to follow the same procedures as the plaintiffs Friedlander and Ronis.

Dated: New York, New York
February 6, 1974

ADRIAN P. BURKE
Corporation Counsel
Attorney for Municipal Defts.
1555 Municipal Building
New York, New York 10007
566-0197

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America.

Defendants.

AFFIDAVIT

73 Civ. 2276 (DBB)

STATE OF NEW YORK )
) SS:
COUNTY OF NEW YORK)

SYLVIA BLATT, being duly sworn, deposes and says:

1. I am the Assistant Director, Bureau of Laboratories, Division of Laboratory Improvement of the Department of Health of The City of New York and am in charge of licensing and pro-

ficiency testing and the enforcement of Articles 13, 15, 17 and 19 of the New York City Health Code.

2. This affidavit is submitted in support of the motion made by defendants Joseph Cimino, The Department of Health and the Board of Health of the City of New York, Gordon Chase, and the Health Services Administration (hereinafter referred to as the municipal defendants) for judgment on the pleadings or, in the alternative, for summary judgment.

3. This is a class action brought by four named plaintiffs on behalf of the themselves and all other non-physician self-employed clinical laboratory directors in the City and State of New York against certain named municipal, state and federal health officials and agencies as defendants by service of a summons and complaint on May 25, 1973. Issue was joined by service of an answer on October 4, 1973.

4. Of the four named plaintiffs only Friedlander and Ronis are clinical laboratory directors licensed by the Department of Health of the City of New York and authorized to direct clinical laboratories in the City of New York.

5. Plaintiffs allege 3 causes of action against the municipal defendants:

a) that the performance and proficiency testing required by Article 13 of NYC Health Code violates due process because plaintiffs are required to use their own equipment, material, reagents, etc. and because the municipal defendants

provide "faulty and ill-prepared artificial specimens; and plaintiffs seek $1,000,000.00 as compensation;

b) that municipal defendants be enjoined from violating plaintiffs' rights to due process in this manner; and

c) that municipal defendants be enjoined from violating plaintiffs' rights to equal protection by exempting from licensing and performance testing requirements the following groups:

i) practicing physicians who perform laboratory tests solely in treating their own patients,

ii) groups of physicians operating clinical laboratories, and

iii) practicing physicians who perform laboratory tests on referral from other physicians.

6. The allegations in paragraphs 12, 15 and 16 of the complaint that municipal defendants deliver faked or artificial specimens to plaintiffs for proficiency testing is incorrect. Animal blood, instead of human blood, is used in the specimens, but there is no difference, for testing purposes, between animal and human blood. In fact, whether animal blood or human blood is involved can only be determined by performing a special test for that purpose.

7. The additional allegations in paragraphs 12, 15 and 16 that municipal defendants deliver "faulty and ill-prepared specimens: incapable of accurate testing including poor, stained,

unreadable slides" is inaccurate and misleading. NYC Health Code §13.25(f)(1) prohibits reporting on a specimen if it is unsatisfactory for testing or inappropriate for the test requested and §13.25(g) requires that any such specimen be returned and that the laboratory notify the department of the reason.

On only one occasion was a specimen returned because it was unsatisfactory for testing by any of the plaintiffs. A copy of the report from Harry Ronis, dated 9-30-71, on the one occasion when he returned a specimen is annexed as Exhibit 1. On that occasion, the laboratory was excused from performing that test without any penalty.

Plaintiff, Daniel Friedlander, never returned a specimen as unsatisfactory.

8. The allegation in paragraph 12 of the complaint that the City of New York had been supplying reagents for prothrombin time tests until they recently began requiring plaintiffs to use their own reagents is incorrect. The City had never supplied reagents for prothrombin time tests until 1972.

In 1972 the Department of Health conducted an experiment to determine whether variations in prothrombin time tests results existed because laboratories used different reagents. In order to control the experiment the Department supplied the same reagent to all laboratories. This experiment was conducted only during 1972 and after the experiment ended, the Department again required that the laboratories use their own reagents.

The results of this experiment are now being examined. In fact, the World Health Organization has expressed great interest in this experiment.

Since that 1972 experiment, clinical laboratories have been sent plasma specimens which are standardized against a World Health Organization primary plasma specimen for prothrombin time tests. In addition, they are supplied with a standard "control" reagent and are required to perform two prothrombin time tests on each plasma specimen, one using the standard reagent and the second using the reagent they normally use in performing the test. In this way, the Department of Health can provide each laboratory with valuable information by characterizing the reagent it uses so each laboratory can compare and conform its results with those of any laboratory using different reagents. Thus if a patient requires continued monitoring, uniform results of his tests can be provided even though tests are performed by different laboratories using different reagents.

9. All clinical laboratories, hospital or independent, whether they have non-physician self-employed directors or physician directors, which are authorized to operate in the City are required to perform proficiency tests in each category listed on their permits. The number of specimens to be tested in each category is determined by the federal requirements as established under the Medicare regulations.

No clinical laboratory in the City would be required to perform proficiency testing in each category more than four times per year.

10. In 1972, Friedlander Diagnostic Laboratory, directed by plaintiff Daniel Friedlander, was licensed to perform laboratory tests in the categories of chemistry, ABO, and R-H typing, Hematology, Microbiology and Syphilis Serology and was required to perform proficiency testing in those categories.

Following is a list of the number of proficiency tests Friedlander was required to perform in 1972 in each category, the number of specimens contained in each category, and the maximum medicaid fee allowed to be charged for all the specimens required to be tested in each category:

Chemistry - 2 proficiency test occasions which consisted of 5 determinations each at maximum allowable medicaid fee of $36.80.

ABO and R-H Typing - 1 proficiency test occasion consisting of 4 specimens each requiring 3 tests at maximum allowable medicaid fee of $19.20.

Hematology - 3 proficiency test occasions consisting of 11 determinations each at maximum allowable medicaid fee of $56.40.

Microbiology - 1 proficiency test occasion requiring testing of 4 specimens at maximum allowable medicaid fee of $7.60.

Syphilis Serology - 1 proficiency test occasion consisting of 6 specimens at maximum allowable medicaid fee of $12.

For the entire year of 1972 the total fees Friedlander would have been allowed to charge under medicaid regulations for the tests it was required to perform under the Department of Health's proficiency testing regulations was $132. Incidentally, if Friedlander had been required to perform the maximum of four tests in each category the total figure would have been $298.80.

11. Also in 1972, Nassau Diagnostic Laboratory, directed by plaintiff, Harry Ronis, was licensed to perform laboratory tests in the same categories as Friedlander and was required to perform proficiency testing in those categories. However, in the categories of chemistry and microbiology, Ronis was required to perform tests on four additional specimens in those two categories because he provided those additional services to physicians.

The total fees which Ronis would have been allowed to charge under medicaid regulations for the tests required by the proficiency testing regulations would be the same as for Friedlander with the addition of $25.60 and $33.60 for the four additional specimens in the chemistry and microbiology categories respectively for a total amount of $191.20. If Ronis had been required to perform the maximum number of four tests in each category, the total figure would have been $425.20.

12. The maximum fees established by the medicaid regulations for laboratory tests give some indication of the cost of performing those tests except that the medicaid fees contain a built-in profit factor. Therefore, the cost of performing those tests would actually be less than the allowable medicaid fee for each test. Thus the total cost to Friedlander and Ronis to perform the proficiency testing required by the municipal defendants in 1972 was less than $132 and $191.20, respectively.

13. A survey of the performance tests of clinical laboratories in New York City which was conducted by the NYC Department of Health between 1960-1964, showed that the performance of a majority of the clinical laboratories was unsatisfactory (see chart from article by Morris-Schaeffer, M.D., Director of Bureau of Laboratories of NYC Department of Health, 81 Public Health Reports 71, 73 (1966), annexed as Exhibit 2).

14. I was a member of the panel which between 1965-1967, conducted a survey of the clinical laboratory proficiency testing and improvement program developed by the NYC Department of Health. The program used two methods to improve laboratory competency and accuracy; on-site consultations by experts and workshop instruction in Health Department laboratories.

Laboratories were placed into two groups for evaluation purposes - a "Control" group which were tested without receiving any benefit of the improvement program and a "test" group which

did receive program treatment. Performance test specimens were delivered to both groups.

These two methods used in the improvement program resulted in no appreciable improvement in the "test" group compared with the "control" group. But, when the proficiency test results of both groups at the beginning of the study are compared with those at the completion of the study, it was apparent that improvement in competency and accuracy was effected simply by the proficiency testing procedure alone. This study emphasized the fact that repeated proficiency testing of laboratories results in improvement in laboratory accuracy.

15. Annexed as Exhibits 3, 4, 5 and 6 are charts which show the competency ratings of control and test group laboratories at various stages of the improvement program. The charts are taken from a report of the study published in 7 Health Laboratory Science, No. 4, pp. 242-255. The charts demonstrate that improvement was made in both the control and test group laboratories indicating that frequent proficiency testing was responsible for the improvement.

16. Thus it is seen that the requirements of proficiency testing in the NYC Health Code is a necessary and reasonable method for the control and regulation of clinical laboratories. Only through this proper control and regulation will the health, welfare and safety of the public be protected.

The cost of performing proficiency testing by clinical laboratories is minimal when compared with the protection afforded the public health and welfare. Proficiency testing is, therefore, a reasonable method for controlling and regulating clinical laboratories, identifying those which are unsatisfactory in accuracy and performance, and also as a method of producing improvement in clinical laboratory performance.

For these reasons the requirement of proficiency testing must be upheld and plaintiffs' action dismissed.

17. The allegations that the City Department of Health permits groups of physicians to operate clinical laboratories and that it permits physicians to operate private laboratories to perform tests on referral from other physicians, both in violation of licensing and proficiency testing requirements (Complt., pars. 26 & 27) are incorrect. Section 13.03 (a) of the NYC Health Code provides that Article 13 "is applicable to all clinical laboratories operating within the limits of the City of New York except a clinical laboratory maintained by the State of New York or the Government of the United States or by a licensed physician who performs test....solely in connection with the treatment of his own patients." Article 13, therefore, is applicable to the two groups referred to by plaintiffs in paragraph 26 and 27 of the complaint.

If any clinical laboratories are operating in violation of the requirements of Article 13 it is only because the municipal

defendants are unaware of any such violation. In fact, if any complaint concerning a violation is registered, it is immediately investigated. If any of the plaintiffs will supply my office with the name and location of any clinical laboratory claimed to be violating Article 13 of the NYC Health Code, an investigation of the complaint will be made. Thus far, no such complaints have been made by any of the plaintiffs.

18. Plaintiffs' allegations that NYC Health Code §13.07 (a)(2) delegates to private organizations the authority to certify individuals as qualified laboratory directors is incorrect. That section provides that "(a) no person shall act or be employed as a clinical laboratory director unless he (1) possesses a certificate of qualification issued by the Commissioner or (2) is certified by the American Board of Pathology, the American Board of Microbiology, or other such certifying board sponsored by an accredited national professional society and approved by the Department." The Boards referred to have the identical requirements as are enumerated in §13.07(1)(3) and in addition, require that the candidate pass an examination in order to qualify for certification.

Furthermore, the two plaintiffs who operate clinical laboratories within the City of New York were granted certificates of qualification pursuant to §13.07(5) "grandfather clause." Neither Daniel Friedlander nor Harry Ronis have been denied a

a certificate of qualification to act as a clinical laboratory director and therefore are not aggrieved and have no standing to raise this issue.

19. Clinical laboratory practice is a very complicated field. One of the reasons for this is that the clinical laboratory operator or director does not treat the patient and is not familiar with or have access to the patient's medical history and cannot therefore relate the results of a laboratory test to the patient's condition.

On the other hand, a physician who treats the patient and performs or supervises performance of laboratory tests can relate the test results to the patient's history and condition. This knowledge can alert the treating physician to any obvious errors in the test results and to the need for a retest.

This is one reason why the classification of NYC Health Code §13.03(a) is reasonable and practical and should not be upset.

WHEREFORE, municipal defendants respectfully request that their motion for judgment on the pleadings or for summary judgment be granted together with such other relief as the Court may deem just.

/S/ _____

Sworn to before me this
6th day of February, 1974.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health,Education and Welfare of the United States of America,

Defendants.

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ANSWER

73 Civ. 2276 (DBB)

Defendants, HOLLIS S. INGRAHAM, M.D., the Department of Health of the State of New York and the Public Health Council of the Department of Health of the State of New York, by their attorney, LOUIS J. LEFKOWITZ, Attorney General of the State of New York, for their answer to the complaint herein.

FIRST CAUSE OF ACTION

1. Admit the allegations of paragraph 1 of the complaint.

2. Deny the allegations of paragraph 2 of the complaint.

3. Deny knowledge or information sufficient to form a belief as to paragraphs 3 and 4 of the complaint.

4. Admit the allegations contained in paragraph 5 of the complaint.

5. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraphs 6 and 7 of the complaint.

6. Admit the allegation of paragraph 8 of the complaint.

7. Deny knowledge or information sufficient to form a belief as to the truth of the allegation of paragraph 9 of the complaint.

8. Deny the allegations of paragraph 10 of the complaint.

9. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraphs 11, 12, 13, 14, 15 and 16 of the complaint.

10. Deny the allegations of paragraph 17, 18, 19 and 20 of the complaint.

SECOND CAUSE OF ACTION

11. Repeat and reallege the answers to paragraphs 1-20 of the complaint in the same manner as originally answered herein.

12. Deny knowledge and information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the complaint.

THIRD CAUSE OF ACTION

13. Repeat and reallege the answers to paragraphs 1-22 of the complaint in the same manner as originally answered herein.

14. Deny the allegations of paragraphs 24, 25 and 26 of the complaint.

15. Deny knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 27 and 28 of the complaint.

16. Deny the allegations of paragraphs 29, 30, 31 and 32 of the complaint.

FOURTH CAUSE OF ACTION

17. Repeat and reallege the answers to paragraphs 1-32 of the complaint in the same manner as originally answered herein.

18. Deny the allegations of paragraph 34 of the complaint.

19. Deny knowledge or information sufficient to form a belief as to the allegations of paragraphs 35 and 36 of the complaint.

20. With respect to paragraphs 37, 38, 39 and 40 of the complaint, admit plaintiff's allegations only to the extent that they reflect the verbatim content of the statutes cited therein.

21. Deny the allegations contained in paragraphs 41, 42, 43, 44, 45 and 46 of the complaint.

FIRST AFFIRMATIVE DEFENSE

22. The Court lacks jurisdiction over the subject matter of this action.

SECOND AFFIRMATIVE DEFENSE

23. The complaint fails to state a cause of action upon which relief may be granted.

WHEREFORE, defendants HOLLIS S. INGRAHAM, M.D., the Department of Health of the State of New York and the Public Health Council of the Department of Health of the State of New York seek judgment dismissing the complaint herein and for such other and further relief as this Court deems justified.

LOUIS J. LEFKOWITZ
Attorney General of the State of New York
Attorney for Defendants Ingraham, Department of Health of the State of New York and the Public Health Council of the Department of Health of the State of New York
By

JEROLD PROBST
Assistant Attorney General
Office & P.O. Address
Two World Trade Center
New York, New York 10047
Tel. (212) 488-7590

NOTICE OF MOTION

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS and STANLEY WEINREB, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

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NOTICE OF MOTION

73 Civ. 2276 DBB

SIRS:

PLEASE TAKE NOTICE that upon the complaint heretofore filed herein, the affidavit of WILLIAM KAUFMANN, M.D., the Rule 9(g) statement attached hereto, and the accompanying memorandum of law, the undersigned will move this Court before the Honorable

NOTICE OF MOTION

DUDLEY B. BONSAL, United States District Judge, in Room 1505, United States Court House, Foley Square, City of New York on the 28th day of January, 1974 at 9:30 o'clock in the forenoon of that day or as soon thereafter as counsel may be heard for an order pursuant to Rule 12(c) of the Federal Rules of Civil Procedure granting judgment on the pleadings, or, in the alternative, for an order pursuant to Rule 56(b) granting summary judgment to defendants Ingraham, New York State Department of Public Health and Public Health Council, and for such other and further relief as may be just and proper.

Dated: New York, New York
January 14, 1974

Yours, etc.,

LOUIS J. LEFKOWITZ
Attorney General of the State
of New York
Attorney for defendants
Ingraham, New York State
Department of Public Health
and Public Health Council
By

/s/
JEROLD PROBST
Assistant Attorney General
Two World Trade Center
New York, New York 10047

NOTICE OF MOTION

TO: ROTHBLATT, ROTHBLATT,
SEIJAS & PESKIN, ESQS.
232 West End Avenue
New York, New York 10023
Stephan Peskin, Esq.

NORMAN REDLICH
Corporation Counsel
Municipal Building
New York, New York 10007
David Fisher, Esq.

PAUL CURRAN, ESQ.
United States Attorney
Southern District of New York
United States Court House
Foley Square
New York, New York 10007
Stephen J. Glassman, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS and STANLEY WEINREB, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

RULE 9(g) STATEMENT

73 Civ. 2276 DBB

STATEMENT OF STATE DEFENDANTS PURSUANT TO RULE 9(g)

Defendants Ingraham, New York State Department of Health and Public Health Council contend that there is no genuine issue of material fact as to any of plaintiffs' claims.

RULE 9(g) STATEMENT

Dated: New York, New York
January 14, 1973

LOUIS J. LEFKOWITZ
Attorney General of the State
of New York
Attorney for defendants
Ingraham, New York State
Department of Public Health
and Public Health Council
By

/s/
JEROLD PROBST
Assistant Attorney General
Office & P.O. Address
Two World Trade Center
New York, New York 10047
Tel. (212) 488-7590

AFFIDAVIT OF WILLIAM KAUFMANN, M.D.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

AFFIDAVIT

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America; and the Department of Health, Education and Welfare of the United States of America,

Defendants.

---

William Kaufmann, M.D. being duly sworn, deposes and says:

1. He is the Director of the Clinical Laboratory Center in the Division of Laboratories and Research of the New York State Department of Health. The Center administers the laboratory improvement program provided for under Article 5, Title V of the Public Health Law of the State of New York outside of New York City.

This laboratory improvement program came into being because it had been demonstrated nationally over a period of years

that clinical laboratory work was being performed at a potentially dangerous low level as a result of inaccuracy in testing, inadequacy of instrumentation, lack of fundamental scientific knowledge and outright fraudulence. This practice was widespread. The result was a public health problem of major proportions. How serious the problem was in New York State can be gleaned from the fact that in the first three years following implementation of Article 5, Title V of the Public Health Law, 51 laboratories out of a total of approximately 400 operating in the State outside of New York City were closed because of their inability to meet even the minimal standards then set by the State. Many of the remaining laboratories, which were permitted to stay open, were doing marginal quality laboratory work.

To assure the public high-quality, accurate laboratory work on which physicians can rely in arriving at diagnoses of their patients' ailments so that they can treat them effectively, Article 5, Title V, enacted in 1964 and made operational on July 1, 1965, provides for a system of granting permits to qualified laboratories; requiring laboratory directors to meet specified qualifications; sending investigators periodically into the laboratories to inspect their facilities, equipment, supplies, personnel and procedures for conformance with acceptable laboratory standards; conducting a proficiency testing program by requiring all laboratories to analyze test samples or specimens

submitted to them by the Center; advising the laboratories of their deficiencies as revealed by the proficiency testing program; assisting them to correct such deficiencies through educational programs and assistance from the investigator and other personnel of the Center; and if a laboratory is unable, during a reasonable period of time, to correct deficiencies and operate in an acceptable manner, refusing to renew its annual permit or commencing enforcement proceedings if it continues to operate without a permit.

To upgrade the quality of laboratory work, the Center conducts educational programs to keep laboratories abreast of advances in laboratory practice and to improve their ability to perform those laboratory tests and procedures in which many laboratories in the State are deficient as shown by the results obtained from the proficiency testing program. Such educational programs include bench training at the Center for personnel of these laboratories, lectures, seminars and workshops held throughout the State by members of the Center's staff as well as personnel of the Bureau of Laboratories of the City of New York. In addition, qualified individuals from the various universities and medical schools in this State frequently participate in these educational programs.

2. The proficiency testing program involves the Center's submitting to all laboratories specimens which have been care-

prepared, scientifically checked for their quality and intensely tested by state and national reference laboratories. This testing must be done in conjunction with and simultaneous to the daily routine testing of specimens submitted to the laboratory by physicians using the laboratory services. Thus, the test specimen actually becomes a routine specimen, usually identical or at least scientifically similar to it, not only testing the laboratories' ability to perform but giving the laboratory an unequaled opportunity to check on its own quality of daily performance. A particular laboratory's permit authorizes it to perform in one or more categories of laboratory tests or procedures such as clinical chemistry, bacteriology, general serology, hematology, parasitology, toxicology, transfusion services - blood grouping and Rh typing, tissue pathology, exfoliative cytology, biophysics and others.

Test specimens obtained from the same material, and therefore alike, are sent not only to the laboratories under permit but also to so-called "reference laboratories". These are laboratories which by years of experience and their national reputation are highly qualified to perform tests in particular categories.

It is important to note that like test specimens are sent not to one such reference laboratory but to a specified number of them. Such reference laboratories test these specimens and arrive at definitive determinations as to their composition. By comparing the determination of the permit laboratory being tested with

those of the reference laboratories testing like samples, it is possible to determine how closely the permit laboratory can come to the values obtained by the reference laboratories. In most cases, if the laboratory's results are within one standard deviation of the mean of the determinations of the reference laboratories, they are judged to be good. Results between one and two standard deviations are generally acceptable but results of three or more standard deviations are unacceptable.

It is important to use a number of reference laboratories simply because slight deviations from the target value are possible and this is expressed in standard deviations. Such standard deviations cannot be allowed to be too wide lest the results become unacceptable or even life endangering. Thus, determinations by not one but many laboratories is made with the greatest possibility of accuracy.

It is not enough to simply inspect a single laboratory in terms of its facilities, equipment, instruments, supplies, reagents, procedures, personnel, quality control efforts, etc. to determine whether it is doing accurate laboratory work. It is necessary that its results be compared with those of other laboratories, particularly those of other excellent laboratories - the reference laboratories - to determine how proficiently it is able to perform the various tests it is authorized to do.

For the most part, specimens used to test laboratory proficiency, are materials derived from the human or animal body

thoroughly checked for their components. A relatively small number are prepared in the laboratory synthetically rather than being of human or animal origin. These specimens, described as artificial or fake specimens in the complaint, are used when the corresponding specimen from the body is sufficiently unstable so that if it were submitted for testing under the proficiency testing program its composition could differ at each reference and permit laboratory at the time of testing and render it useless for proficiency testing. Such specimens prepared by the Center are substantially the same in composition as the human specimen for which they are used as substitutes and are a good test of a laboratory's proficiency in testing the comparable human specimen. This is based upon thorough scientific evaluation over the years by nationally and internationally recognized authorities in the clinical laboratory field. This type of specimen constitutes a small percentage of specimens which laboratories are required to test under the proficiency testing program. Once prepared, they are processed as are specimens from the human body.

It is possible for any specimen to deteriorate or become contaminated so that it is different from what it was originally. Such change in the composition of the specimen would manifest itself in the results obtained by the reference laboratories and for that matter, by the laboratories under permit, and the particular test results would not be used by the Center in evaluating

proficiency. It is important in day to day laboratory work for a laboratory to be able to determine that a particular specimen submitted by a physician has deteriorated or become contaminated and therefore should not be tested. In the rare event a Center test specimen is thus changed from its original state, it may be useful to know whether a laboratory has the capability to determine that such an event had actually occurred.

A small percentage of test specimens are stained on slides. These slides are prepared in the Center by personnel who are more qualified to prepare good slides than most physicians or their employees who submit such stained slides for examination by these laboratories. The stains are good and they are readable. They undergo the same testing by reference laboratories as those mentioned above. There are different methods of staining slides and some laboratories experience difficulty not because the staining is poor but because they are not acquainted with the particular method used. Once this deficiency is discovered by Center personnel, it can be corrected by educating the laboratory personnel involved. It is important that they have such ability because such a staining method may be used by physicians as to slides submitted by them for testing. Such slides are thus a good test of a laboratory's ability to perform its day to day work. If a slide were so poor that it was in fact unreadable, it would be unreadable by the reference laboratories and therefore would not

be used by the Center in judging a laboratory's proficiency in performing that procedure.

It is obvious that in order to conduct a meaningful proficiency testing program and to determine a permit laboratory's capability to perform, one must not only determine the personnel's capability but also the adequacy of equipment, materials, reagents and instruments used by the permit laboratory in its daily routine to ascertain the reproducibility, precision and accuracy of its performance. On this performance depends the physician's diagnosis and frequently hangs the patient's life. Since by doing so the proficie .cy test specimen becomes just another routine specimen in the daily work of the laboratory, the cost of performance in terms of reagents used and personnel time employed is minimal. The use of unsatisfactory reagents, poorly calibrated instruments and deficient equipment are common causes of poor test results. The cost of materials and reagents used and wear and tear on equipment necessitated by the proficiency testing program is exceedingly small and the cost is small and eminently reasonable price for a laboratory to pay in order to learn and to assure itself, the physician and the public that it is doing acceptable laboratory work.

It is conceivable that a laboratory has so little confidence in its day to day performance that it chooses to spend inordinate amounts of time testing the samples submitted by the Center. This

is a practice the Center clearly disapproves of because it would be definitive proof that the laboratory itself is not confident of its own proficiency in the performance of its daily routine work done on human specimens submitted for the explicit purpose of aiding the physician in the diagnosis and treatment of disease. Such practice in itself would be sufficient proof to seriously question the laboratory's ability to perform.

Attached as exhibit A are the Proficiency Testing Results of Beach Medical Arts, Plaintiff Jacobs' laboratory and Plainview Clinical Laboratory, Plaintiff Weinreb's laboratory. Since these laboratories have performed successfully in the proficiency testing program over the years, whether the test samples submitted to them be characterized as fake, ill-prepared, faulty or unreadable, they must have been capable of accurate testing. Whatever difficulty these laboratories had in performing tests over the years was less than the usual difficulty laboratories have in performing tests in their day to day practice where some tests are harder to do than others and some specimens are not in as good condition as others.

It was and still is common for the better laboratories, voluntarily and at very considerable expense, to participate in proficiency testing programs before such participation was required by the State of New York and other governmental jurisdictions. All reputable clinical laboratories at their own expense have

established and participate in national and professional proficiency testing programs for the very purpose of ascertaining reliability of results. The cost incurred in these programs is considered essential and unavoidable to assure accuracy just as it is required and done in all other aspects of scientific endeavors. While a rare laboratory may not care to know how well it is performing, the State of New York has the obligation to ascertain that the public will not be harmed because of inaccurate and misleading laboratory work.

3. The value of the proficiency testing program goes beyond protecting life and safeguarding public health. In the conduct of the program, information is obtained as to how well or how poorly laboratories generally are performing particular tests as well as to the cause or causes of this poor performance.

Thus on investigating why some laboratories do well in performing a particular test and others do poorly, the Center may find that the use of one particular commercial reagent rather than another was the cause of the difference between success and failure. This information would be circulated among all the permit laboratories including those which had done poorly, and they could then switch reagents. In like manner, the Center might determine that a particular method of conducting a test was superior to an alternative method in use. The type of instrument used might be the decisive factor. Accuracy with which instruments were cali-

brated might be the determining factor. In a particular case, automated equipment might yield better results than the manual performance of tests. The training and experience of laboratory personnel might be found by the Center to account for good results, and educational programs for personnel of laboratories that had fared badly would be provided by the Center. Bad results might have resulted from inability of the staff to properly read and interpret data which also would result in educational programs by the Center to correct that deficiency. Poor quality control programs of laboratories which did poorly might be found by the Center to be responsible for their unacceptable performance.

The proficiency testing program is thus not only a reasonable and important public health measure but even a necessary and essential one since without it physicians would never know whether or not the results reported by the laboratories are reliable in assessing a patient's condition or the physician's treatment of the condition.

Abolition of a proficiency testing program which is recognized as a prototype not only by other states but by the federal government and even abroad would be like turning the clock back, not recognizing the advances that have been made in the combat against disease and in the protection of the public health; it would furthermore set back progress in these fields.

WILLIAM KAUFMANN, M.D.

Sworn to and subscribed before me
this 12th day of October, 1973.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER W. WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

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AFFIDAVIT

73 Civ. 2276 (DBB)

STATE OF NEW YORK )
) SS:
COUNTY OF NEW YORK)

ROSE L. BERMAN, being duly sworn, deposes and says:

I am a self-employed clinical laboratory director and a member of the class represented by the named plaintiffs. I make

this affidavit in opposition to the defendants' motion for summary judgment.

I have read the defendants' motions for summary judgment and the affidavits in support of these motions.

I am a scientist, the discoverer of the twenty-four hour rat pregnancy test known as the Frank-Berman Rat Ovarian Hyperemia Pregnancy Test. I discovered this while I was doing endocrine research at Mount Sinai Hospital in New York City.

I have had over twenty (20) scientific papers published in the leading medical journals of this country and in Europe. These papers covered various subjects including bacteriology, tropical medicine, chemotherapy and endocrinology. I was invited by the First International Congress of Gynecology and Obstetrics, held in Geneva, Switzerland, to present a paper and exhibit concerning my pregnancy test. My paper was published in the book "Modern Trends in Gynecology and Obstetrics" published by Librairie de L'Universite, Georg & Cie S.A., Geneve. By invitation, my biography is noted in American Men of Science (renamed American Men and Women of Science), as well as in other American, British, South American, etc. directories. I am a Fellow of the American Institute of Chemists, member of American Association of Clinical Chemists, New York Academy of Science.

I am a (science) college graduate as are all the four plaintiffs.

AFFIDAVIT OF ROSE BERMAN

I have had my own clinical laboratory since 1949, and became a clinical laboratory director in 1956 when the New York City Department of Health code was changed from only an M.D. degree holder, with specified experience qualifications being allowed to be a laboratory director, to include other college graduates with doctorate, master's, or bachelor's degrees, with specified experience qualifications. The two plaintiffs, Messrs. Ronis and Friedlander also met all the qualifications in the 1956 code.

In 1964 the Health Code was changed limiting laboratory directorships to holders of M.D. or Ph.D. degrees. Those persons already licensed were, of course, allowed to continue practicing their profession. That was pursuant to the so-called "grandfather clause" derogatorily referred to by Sylvia Blatt in her affidavit.

The specimens which clinical laboratories are required to test by the Health Department are faulty and ill-prepared. In fact, they are phony and artificial specimens. That only one of the named plaintiffs has returned a specimen as unsuitable for testing does not negate this statement. The faulty specimens may be susceptible to testing. However, they are incapable of accurate testing. A result may be reached, but not an accurate result. There frequently is no way of determining if a specimen is faulty until the testing is performed.

Attached as Exhibit 1-5 is a Syphilis test report of plaintiff FRIEDLANDER and his subsequent notice of an unsatisfactory

evaluation. The New York City Department of Health eventually apologized to Mr. Friedlander (Exhibit 5) and disregarded the test. However, this apology does not reimburse Mr. Friedlander for the time he wasted as a result of the "faulty and ill-prepared specimen." He was able to achieve a result, but he was not able to achieve an accurate result. This is only one example of many such instances of "faulty and ill-prepared specimen" resulting in plaintiffs' loss of their valuable time.

The "faulty and ill-prepared specimens" result in plaintiffs' further wasting their time due to their sense of professional responsibility. If the specimen is "faulty and ill-prepared" and therefore produces an unorthodox test result, the plaintiffs naturally re-check their entire procedure for the particular test to insure that their equipment is not at fault. A responsible clinical laboratory director would investigate all other possible causes for the unusual result before concluding that the specimen is at fault. This results in an unnecessary waste of plaintiffs' time.

The specimens sent to the laboratory for testing do not even conform with the New York City Health Department's own requirements for specimens submitted to its Bureau of Laboratories. Attached as Exhibit 6 is a Form 900N to be submitted by physicians for Rh and Blood Group tests. The form states that Clotted Blood be submitted for testing by the Bureau of Laboratories. Yet the

blood submitted to the laboratories for "proficiency testing" is liquid, not clotted.

I stood for five (5) hours repeating ad nauseum Rh and Blood Group tests on "specimens" for "performance testing", repeating endlessly for I was unable to make readings either macroscopically in test tubes or microscopically. Mr. Goldberg, a Health Department inspector can attest to this, he couldn't make readings either. I was not reimbursed for my wasted time of more than five hours.

Time and again, the labs designated by Sylvia Blatt as "reference labs" came up with different results on performance testing, thus requiring voiding evaluation of these groups of specimens. The laboratories were never reimbursed for the waste of time and materials used in these faulty "performance" specimens sent to labs for testing.

Until recently, the plaintiffs have never been required to use their own reagents for prothrombin time tests.

Paragraph 8 of the affidavit of Sylvia Blatt in support of defendants' motion admits that the "Department of Health conducted an experiment" involving prothrombin time tests. The work for this experiment was thus supplied free to the Department of Health which conducted this experiment under the guise of and in the context of proficiency testing. The plaintiffs should not be so forced to perform such free labor for the Department of Health.

The defendant contends that there is a "built-in profit factor" in medicaid. Any such "built-in profit factor" has been more than negated by the current inflationary trend of the economy. In fact, that entire medicaid fee structure is currently under attack by the hospitals of New York. The hospitals have brought legal action claiming that the fees are insufficient. On April 27, 1974 Justice Abraham Gellinoff of the New York State Supreme Court ruled that the state must reimburse hospitals, through medicaid, at a rate "reasonably related to the costs of efficient production of such service." The Justice annulled the reimbursement rate that had been applied for 1973 and ordered a revision in line with reasonable costs.

In addition, many laboratories do not accept medicaid work since the fees are considered inadequate to cover costs.

The affidavit of Sylvia Blatt deceptively states that the clinical laboratories can return faulty specimens pursuant to Section 13.25(f) and (g). The affidavit implies that those sections exist for that very purpose. On the contrary, those sections were added as part of remedial regulations designed to combat the evils of laboratories which solicited specimens to be sent via the mail in this state and across the country as well. Those laboratories solicited mail-order tests from physicians even though, in many cases, the particular tests involved have to be performed within an hour or even less of specimen-taking.

In any case, the code sections would not aid a laboratory when the "performance testing" specimens are not apparently faulty and are discovered to be faulty only after testing and repeated re-checking.

Pursuant to its directive dated August 21, 1972, the New York City Department of Health now permits podiatrists to perform certain laboratory tests in their offices (attached as Exhibit 7). These podiatrists are not subject to performance testing although a clinical laboratory performing such tests is subject to performance testing.

The New York City Health Code, §13.03 which exempts physicians performing tests in their offices for their own patients, does not exempt podiatrists.

The following physicians operate private laboratories for other than their own patients and do not have laboratory permits, pay permit fees, or engage in proficiency testing:

1. Dr. Robert L. Rosenthal
   48 East 91 Street
   New York City

2. Dr. Mary C. Tyson and Dr. Frank Bassen
   654 Madison Avenue
   New York City

3. Dr. Carl Reich
   19 East 80 Street
   New York City

4. Dr. George Brancato
   449 Bay Ridge Parkway
   Brooklyn

5. Dr. Lawrence Cotter
48 East 64 Street
New York City

Three years ago I gave the Department of Health the names of these physicians. The defendant has not acted to enforce its regulations.

The following Health Insurance Plan (HIP) groups comprised of over one thousand (1,000) physicians conduct laboratory tests on their own premises. None of these groups have laboratory directors or permits, pay permit fees, or engage in proficiency testing:

Manhattan

Central Manhattan Medical Group (HIP)
65 West 55th Street
Metropolitan-Hudson Medical Group (HIP)
6 West 86th Street
Yorkville Medical Group (HIP)
158 East 84th Street
Lower Manhattan-Gramercy Medical Group (HIP)
781 Broadway (at 185th Street)
Washington Heights Medical Group (HIP)
4337 Broadway (at 185th Street)
New York Medical Group (HIP)
324 East 23rd Street
Upper Manhattan Medical Group (HIP)
1865 Amsterdam Avenue
Circle Manhattan Medical Group (HIP)
123 West 79th Street

Bronx

Central Bronx Medical Group (HIP)
16 East 169th Street (Jerome Avenue)
East Bronx Medical Group (HIP)
2590 Frisby Avenue

Northern Medical Group (HIP)
Co-Op City Center, 100 Asch Loop
Southern Medical Group (HIP)
326-8 East 149th Street

Brooklyn

Central Medical Group of Brooklyn (HIP)
345 Schermerhorn Street
Brooklyn Medical Group (HIP)
153 Pierrepont Street
Flatbush Medical Group (HIP)
1000 Church Avenue (Coney Island Avenue)
Empire Medical Group (HIP)
550 Eastern Parkway (Nostrand Avenue)
Kings Highway Medical Group (HIP)
3245 Nostrand Avenue (corner of Ave. S)
Parkway Medical Group (HIP)
1235 Linden Boulevard
Midboro Medical Group (HIP)
1783 Bedford Avenue
Bay Ridge Medical Group (HIP)
6740 Third Avenue
Bedford-Williamsburg Medical Group (HIP)
1143 De Kalb Avenue

Queens

La Guardia Medical Group (HIP)
88-22 161st St., Jamaica (Plus 7 Sub Centers)
Central Flushing-Upper Queens Medical Group (HIP)
59-25 Kissena Blvd.
Central Flushing Center (HIP)
135-40 39th Avenue

I have previously given the names of these groups to the defendant New York City Department of Health. The defendant has not acted to enforce its regulations.

A secret agreement was entered into between the HIP central office and the defendant New York City Department of Health to

allow individual HIP groups to perform certain laboratory tests at the group locations, in violation of the New York City Health Code. These HIP groups maintain a central laboratory facility for the performance of tests; however, the individual locations perform various tests in violation of the Code on their own premises. These individual HIP groups pay no permit fees, do not have qualified laboratory directors, and are not subject to performance testing.

As another example of its failure to enforce its regulations, the New York City Health Department was informed by me of the illegal existence and illegal operation of two laboratories operating under the name of Scientific Medical Systems, Inc. These laboratories operated without a permit and did not engage in the Department program of proficiency testing. Despite having knowledge of their existence, the Department took no action for over fifteen months after which summonses were finally served on employees of the laboratories but not on the owner, a physician Dr. Joseph Feldshuh. Because of this, the cases were ultimately dismissed by the court and the department was directed to serve Dr. Feldshuh and the owner corporation.

The following are laboratories operated by the Human Resources Administration of the City of New York. These laboratories do not have qualified laboratory directors, or laboratory permits, do not pay permit fees, and are not subject to proficiency testing:

1. Qualicap Family Planning
   42-15 Crescent Street
   Long Island City

2. Bushwick Family Planning
   1407 Myrtle Avenue
   Brooklyn

3. Coney Island Pediatric and Family Life Clinic
   2836 West 23rd Street
   Brooklyn

4. Crown Heights Community Health Association
   1167 Nostrand Avenue
   Brooklyn

5. Mid-Brooklyn Health Society
   1228A-1232 Broadway
   Brooklyn

6. South Brooklyn Multi-Purpose Self Help Clinic
   141 Nevine Street
   Brooklyn

7. United Parents
   1011 Sulter Avenue
   Brooklyn

8. Varet Street Tenants Association
   94 Manhattan Avenue
   Brooklyn

These laboratories all perform tests for which the plaintiffs are subject to proficiency testing. Human Resources Administration laboratories are operated by totally unqualified personnel. I have been personally informed by the personnel of these laboratories that unqualified neighborhood people are hired and "trained" to perform laboratory tests. This entire procedure is done without any regulation by the defendant New York City Department of Health. These laboratories have no lab permits.

They do not have lab directors and are not subject to performance testing.

The following facilities operate illegal laboratories on their premises, do not pay permit fees, do not have qualified laboratory directors, are not subject to performance testing, all reported by me as far back as 1972:

St. Mark's Clinic
44 St. Mark's Place
New York City

The Door
12 East 12th Street
New York City

Harlem Medical Associates
216 West 138 Street
New York City

The following facilities operate illegal laboratories. They operate without permits, do not pay permit fees, do not have qualified laboratory directors, and are not subject to performance testing:

1. Planned Parenthood Center
1120 Genesee Street
Syracuse, New York

2. Dobbs Ferry Group
Ashford Avenue
Dobbs Ferry, New York

3. Monsey Medical Group
29 Main Street
Monsey, New York

The Dobbs Ferry Group laboratory still operates at the same address as one office but under the individual names of Dr. Robert Dorsen, Dr. Jerome Quint, and Dr. Donald Perleman. I have previously reported these laboratories to the New York State Department of Health, and no action has been taken to enforce state regulations.

There is no basis for any determination that a physician or podiatrist is qualified, by virtue of degree alone, to perform laboratory tests yet the law and the enforcement policy of the State and City defendants allows these individuals carte blanche.

In 1972 the defendant New York State Health Department offered physicians in private practice an opportunity to become clinical laboratory directors. Dr. William Kaufmann of the New York State Department of Health informed me that over 200 physicians applied for permits and all were rejected as unqualified. Yet, under the current law and regulations, these physicians along with more than 34,000 other M.D.'s in this state can continue to perform tests for their own patients.

Physicians doing laboratory tests in their private office are not regulated or controlled by their own societies.

Attached are copies of letters I, on behalf of the Clinical Laboratory Directors of New York State, Inc., wrote to the Medical Society of the State of New York and other individuals.

These letters indicate a pattern of overcharging by physicians who utilized the services of "contract laboratories" (unlimited numbers of lab tests for a small fee payable by doctors to such labs; this is not outlawed by chapter 971 of the laws of 1970); physicians charging patients for free tests performed by New York City Health Department; plus incorrect lab reports of "contract" labs. As indicated in the correspondence, the Medical Society took no action whatsoever to remedy these abuses (Exhibit 8).

Regarding Sylvia Blatt's statement, point 19, this is not correct. All a clinical laboratory needs is a properly collected specimen on which to perform the tests requested by patient's physician. We do not need history of examination findings on patient. I shall illustrate the fallacy of her statement by two examples from amongst hundreds that I can cite regarding all kinds of lab tests.

I have performed many tests on referral from physicians after which I have been told that, based on the physician's examination, my results were in error. Sometime later, and to the detriment of the patient, the physician discovered that his examination and not my test was wrong.

For example, Dr. Samuel Weinbaum, of New York City, referred his sister-in-law to me for a pregnancy test. Her husband brought the urine specimen to me. I never saw the patient. I reported the positive result to the physician. The patient's

husband brought two more urine specimens, in all three pregnancy tests in a period of two weeks, all tests yielding positive pregnancy test results. A few days after I had issued the third pregnancy test result, I received a telephone call from Dr. A. Charles Posner, former Director of the Obstetrics-Gynecology Service at the Bronx Lebanon Medical Center, Director of the Obstetrics Service at Harlem Hospital, and Attending Gynecologist and Obstetrician at Polyclinic French Hospital. He inquired if I would be able to get results to him the next day on "titres" pregnancy tests (this means making many dilutions of the urine specimen and injecting many "dilution" urines into rats). I answered in the affirmative. He told me that he had a properly collected specimen that would be delivered to me, that the patient was a physician's sister-in-law and in view of that he was having another physician, Dr. Howard C. Taylor, Jr., examine the patient the next day in consultation. (Dr. Taylor is former Chief of Obstetrics and Gynecology at Columbia Presbyterian Medical Center and former editor of the American Journal of Obstetrics and Gynecology.) Dr. Posner then gave me the name of the patient, and I advised him that I had done her three previous tests, she being Dr. Weinbaum's sister-in-law.

"Titres" are done to establish the presence of a Hydatidiform Mole, Choriocarcinoma or combination of both these conditions, both being very serious abnormalities of pregnancy. The

next morning I reported to Dr. Posner that all the titres were positive. At 4:00 PM Dr. Posner telephoned me to tell me that Dr. Taylor had examined the patient, his diagnosis being that the patient had a fibroid uterus superimposed with an early pregnancy and Dr. Taylor told him that my test results were completely wrong and so stated in very strong terms. I urged Dr. Posner not to disregard my results.

Two hours after Dr. Taylor had examined the patient, she started to bleed. Dr. Posner called me to advise that he was going to the hospital and would call me from there. He called me to advise that the patient passed a Hydatidiform Mole, that he had curretted her, and packed her with gauze. The next morning, Dr. Posner telephoned me to let me know that the patient was hemmorhaging again and that he would now do a hysterectomy on her. I asked him to please advise me of the pathology of the uterus, that in view of the titres I had done, I was positive that Choriocarcinoma would be in the uterus.

Two weeks later Dr. Posner called me to advise me that he had the six reports from six different pathologists around the country, and that all six reports indicated Choriocarcinoma. He sent a full report to Dr. Taylor who could deduce by himself that his diagnosis was completely wrong and that my test results were completely correct.

In another instance Dr. Benjamin Segal, former Attending

AFFIDAVIT OF ROSE BERMAN

Gynecologist and Obstetrician at Lincoln Hospital and Beth Israel Medical Center, referred a patient to me for a pregnancy test which I reported as positive. The patient came twice more, and I reported these as positive also. Dr. Segal called me to advise that all my three tests were absolutely wrong, that I could throw my pregnancy test out of the window, that he would never again send me patients. It was impossible to even talk to him because he was so angry.

A week later, Dr. Herman Robbins called me to let me know that my tests were completely correct on the patient. I wondered how he knew anything about this and he told me that the patient was his sister-in-law, that two days after my last report went to Dr. Segal, the patient collapsed while at work and was rushed to the hospital, that Dr. Segal operated and found a ruptured ectopic pregnancy (tubal pregnancy).

The evidence indicates a clear pattern of discrimination, exercised by discriminatory laws, regulations and particularly enforcement policy. This discrimination is not reasonable.

ROSE L. BERMAN

Sworn to before me this
12th day of June, 1974.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

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REPLY TO RULE 9(g) STATEMENT

73 Civ. 2276 (DBB)

A genuine issue exists as to the following material facts:

1. Whether or not plaintiffs are required to perform proficiency tests on faulty and ill prepared specimens.

2. Whether or not the state and municipal defendants are purposefully discriminating against the plaintiffs in administering the relevant laws.

DATED: New York, New York
June 27, 1974

Yours, etc.,

ROTHBLATT, ROTHBLATT,
SFIJAS & PESKIN
Attorneys for Plaintiff
232 West End Avenue
New York, New York 10023
(212) 787-7001

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONNIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

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AFFIDAVIT

73 Civ. 2276 (DBB)

STATE OF NEW YORK )
) SS.:
COUNTY OF NEW YORK)

SYLVIA BLATT, being duly sworn, deposes and says:

1. I am the Assistant Director, Bureau of Laboratories, Division of Laboratory Improvement of the Department of Health of the City of New York and am in charge of licensing and profi-

ciency testing and the enforcement of Articles 13, 15, 17, and 19 of the New York City Health Code.

2. This affidavit is made to supplement my affidavit sworn to on the 6th of February, 1974, submitted in support of the motion made by the municipal defendants for judgment on the pleadings or for summary judgment.

3. The Department of Health of the City of New York has continually enforced its clinical laboratories' regulations uniformly in regard to all those who came within the purview of its jurisdiction. This department is not concerned with singling out one group or groups for particularly stringent code enforcement but seeks only to maintain a high standard of performance in the City's licensed laboratories.

4. The affidavit of Rose L. Berman, sworn to the 12th day of June, 1974, contains many inaccuracies:

a. The doctors referred to on p. 6 of Rose Berman's affidavit are not operating private laboratories in violation of the Health Department's regulations. They either perform tests only on their own patients or, in the case of Dr. Lawrence Cotten, perform tests only on specimens from deceased individuals submitted by various medical examiners' offices and therefore do not come within this department's jurisdiction. Dr. Bassen is retired.

b. Rose Berman's allegation at p. 8 that a "secret agreement" has been made between the City and the various Health Insurance Plan Inc. (HIP) groups to operate in violation of the law is untrue. The various HIP groups mentioned by Rose Berman either have laboratory services performed by Centralized Lab Services Inc. of Queens, New York, or under their direct supervision or maintain properly licensed laboratories on their premises.*

c. Scientific Medical Systems Inc., referred to in p. 8 of Rose Berman's affidavit presently operates under the supervision of this department's inspectors and is required to perform all proficiency tests required by law and is awaiting approval of their license.

d. The Family Health Centers listed on pp. 8 and 9 of Rose Berman's affidavit are not run by the

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*The following are the HIP groups, together with their permit numbers which mention properly licensed laboratories on their premises:

| | |
|---|---|
| Central Manhattan Medical Group | Permit #706 |
| Yorkville Medical Group | Permit #607 |
| Circle Manhattan Medical Group | Permit #126 |
| Kings Highway Medical Group | Permit #497 |
| Parkway Medical Group | Permit #663 |
| LaGuardia Medical Group | Permit #636 |
| Central Flushing-Upper Queens Medical Group | Permit #330 |

Human Resources Administration and have all their laboratory tests performed by properly licensed laboratories. My investigation reveals that some pregnancy tests are performed on the premises by doctors on their patients which is permissable under the law.

e. The clinics operating in the City of New York listed on pp. 9 and 10 of Rose Berman's affidavit have tests performed on the premises only by doctors on their patients, with the exception of Harlem Medical Associates [sic] the proper name for this clinic is Upper Harlem Medical Associates] which maintains a properly licensed laboratory on the premises with Permit #598.

/s/
SYLVIA BLATT

Sworn to before me this
5th day of October, 1974.

DECISION

COPY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY ROMIS and STANLEY WEINBERG, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

-against-

73 Civ. 2276

#41508

JOSEPH CURRAN, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, EMILIO S. [illegible], M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

ROTHBLATT, ROTHBLATT, SELNA & PERR Y, ESQS.
232 West End Avenue, New York, N.Y. 10023
Attorneys for Plaintiffs
By HENRY ROTHBLATT, ESQ.

DECISION

ADRIAN P. BURKE, ESQ., Corporation Counsel
Municipal Building, New York, N.Y. 10007
Attorney for Municipal Defendants
DAVID W. FISHER, ESQ.
EDWARD P. MALIA, ESQ.
Of Counsel

HON. LOUIS J. LEFKOWITZ,
Attorney General of the State of New York
2 World Trade Center, New York, N.Y. 10047
Attorney for State Defendants
DAVID SPIEGEL, ESQ.
JEROLD PROBST, ESQ., Asst. Attorneys General,
Of Counsel

HON. PAUL J. CURRAN,
United States Attorney for the Southern District of N.Y.
Attorney for Defendants Weinberger and Department of
Health, Education and Welfare
GREGORY J. DOYLE, ESQ.,
Assistant United States Attorney,
Of Counsel

MEMORANDUM

BONSAL, D. J.

Plaintiffs, suing as a class, allege that they are non-physician self-employed clinical laboratory directors in the City and State of New York. They claim that their rights under the Fifth, Thirteenth, and due process and equal protection clauses of the Fourteenth Amendment to the United States Constitution have been violated because they are required by State law, and within New York City by corresponding City ordinance, to perform proficiency tests on specimens prepared by the City or State defendants. Jurisdiction is asserted under 28 U.S.C. §1343(3).

DECISION

After filing answers denying plaintiffs' allegations, the City and State defendants, consisting of the respective departments of health and their commissioners, each move for judgment on the pleadings pursuant to F.R.Civ.P. 12(c) and in the alternative for summary judgment under F.R.Civ.P. 56. The Federal defendants, the Department of Health, Education and Welfare and its Secretary, filed an answer denying plaintiffs' allegations, but have not filed a motion to dismiss.

THE STATUTES

Title V of the New York Public Health Law and Article 13 of the New York City Health Code provide in pertinent part that each clinical laboratory and its director must obtain permits authorizing the tests it may perform.* To retain its permit, each clinical laboratory must participate in a proficiency testing program under which it is required to analyze chemical specimens sent by the State or City and then to report the results. The results are graded by the appropriate governmental agencies. A laboratory which repeatedly fails to perform sufficiently accurate tests will lose its permit.

* Clinical laboratories outside New York City are regulated by the State Department of Health (N.Y. Pub. Health Law §574(1) (McKinney 1971)) and clinical laboratories within the New York City limits are regulated by the City Department of Health. Id. §574(2).

The state statute exempts from the permit requirement and the proficiency testing program all laboratories operated by a licensed physician, osteopath, dentist or podiatrist who performs or whose employees perform laboratory tests or procedures "solely as an adjunct to the treatment of his own patients." N.Y. Pub. Health Law §579 (McKinney 1971). The New York City Health Code exempts only licensed physicians and their employees who perform tests in connection with the treatment of their own patients. N.Y.C. Health Code §13.03(a).

The New York City Health Code provides in addition that if a laboratory determines that a test specimen is defective or contaminated, it need only report that fact to the City Department of Health and may discontinue the test. Id. §13.25.

THE COMPLAINT

The complaint alleges in the First Cause of Action that the proficiency tests constitute a seizure of property in the form of labor and materials without compensation under color of State law and in violation of due process of law and the Thirteenth Amendment to the United States Constitution. Plaintiffs seek damages in the amount of $1,000,000 from each defendant.

In the Second Cause of Action plaintiffs seek a permanent injunction pursuant to 42 U.S.C. §1983 enjoining defendants from

requiring plaintiffs to perform any further proficiency tests.

In the Third Cause of Action plaintiffs allege that the plaintiff class has been denied equal protection of the laws because they must comply with the testing requirements while licensed physicians (and outside New York City osteopaths, dentists and podiatrists) do not. Plaintiffs also allege that the City and State permit physicians to operate clinical laboratories or perform tests for other physicians' patients in violation of the applicable laws.

DEFENDANTS' MOTIONS FOR JUDGMENT ON THE PLEADINGS

Defendants move for a judgment on the pleadings on the ground that the plaintiffs fail to state a substantial federal question upon which jurisdiction may be founded.

Section 1343(3) of Title 28 of the United States Code gives the federal district courts original jurisdiction of civil actions to redress deprivations under color of State law or ordinance of rights secured by the Constitution. To confer subject matter jurisdiction under section 1343, plaintiffs' complaint must state a constitutional claim "of sufficient substance to support federal jurisdiction." Hagans v. Lavine, 415 U.S. 528, 536 (1974). A claim is "insubstantial" either because it is "'obviously without merit" or because 'its unsoundness so clearly

results from the previous decisions ... as to foreclose the subject and leave no room for the inference that the question sought to be raised can be the subject of controversy.'" Hagans v. Lavine, supra at 537, and cases cited therein.

A. Plaintiffs' Due Process Claims

There is no public policy more important than the protection of citizens from practices which may be injurious to health. See Barsky v. Board of Regents of the University of the State of New York, 347 U.S. 442, 449 (1954). Cf. Mohammad Ali v. Division of State Athletic Commission of the Department of State of the State of New York, 316 F.Supp. 1246, 1250 (S.D.N.Y. 1970). The defendants' permit and proficiency testing programs are essential to protect the public from the consequences of incompetent clinical laboratory testing. To achieve this goal, it is appropriate that the State and City require clinical laboratories to obtain permits based upon proficiency tests. Therefore, these programs are well within the bounds of the State's police power. See North Dakota State Board of Pharmacy v. Snyder's Drug Stores, Inc., 414 U.S. 156 (1973); Williamson v. Lee Optical of Oklahoma, Inc., 348 U.S. 483, 487-88 (1955); S.P.S. Consultants, Ind. v. LaRossa, 333 F.Supp. 1273 (S.D.N.Y. 1971) (3-judge court). See Semler & Sons, Inc. v. Rostetter, 384 U.S. 35, 47 (1966) (deference to legislative choices); McGowan v. Maryland, 366 U.S. 420

(1961); N.Y. Pub. Health Law §570 (McKinney 1971) (legislative purpose). There is also a rational basis for imposing these requirements upon clinical laboratories while exempting office-connected laboratories directed by licensed physicians, osteopaths, dentists and podiatrists. Cf. North Dakota Board of Pharmacy v. Snyder's Drug Stores, Inc., supra; Williamson v. Lee Optical of Oklahoma, Inc., supra.

Plaintiffs' claim that they are deprived of property without just compensation is also without merit. Reasonable regulations restricting the use of property in order to safeguard the public's health do not constitute a compensable appropriation of property for public use. See Goldblatt v. Town of Hempstead, 369 U.S. 590 (1962); New Orleans Public Service, Inc. v. City of New Orleans, 281 U.S. 682 (1930). Plaintiffs therefore must bear the cost of complying with such regulations. Pent-R-Books, Inc. v. United States Postal Service, 328 F.Supp. 297, 310 (E.D.N.Y. 1971) (Judd, J.). See Goldblatt, supra; New Orleans Public Service, Inc., supra. See also 15 U.S.C. §78o(b) (8) (concerning Securities and Exchange Commission); 12 U.S.C. §482 (concerning the expense of examining national banks).

B. Plaintiffs' Equal Protection Claim

Plaintiffs' equal protection claim similarly fails to state a substantial federal question. So long as the statutory

distinction is rational and the statutory classification is based on criteria related to the objective of the statute or has some basis in practical experience, there is no violation of the equal protection clause. See San Antonio Independent School District v. Rodriguez, 411 U.S. 1, 40 (1973); McGinnis v. Royster, 410 U.S. 263, 276 (1973); Dandridge v. Williams, 397 U.S. 471, 486 (1970). A program will not be found arbitrary or irrational merely because the legislature moves one step at a time. Schilb v. Kuebel, 404 U.S. 357, 364 (1971); Williamson v. Lee Optical Co., supra at 489.

The distinction drawn by the State clearly passes this test for rationality. As noted with respect to plaintiffs' due process claim, clinical laboratories have no contact with the patient aside from the specimen taken from his body. Therefore, there is greater possibility that erroneous laboratory results will go undetected than when an attending physician, who knows the patient's symptoms and history, obtains an inaccurate test result.

Plaintiffs' claims that the City and State defendants fail to enforce their statutes also do not represent substantial federal questions upon which federal district court jurisdiction may be based. Plaintiffs fail to allege in their complaint that defendants had knowledge of these violations. Thus plaintiffs

have not alleged all the elements necessary to an equal protection claim. See Snowden v. Hughes, 321 U.S. 1, 8 (1944) (there must be purposeful discrimination by defendants).

If plaintiffs feel that defendants are failing to observe the standards prescribed in the statutes and regulations, they should seek relief from the administrative agencies involved and, if that fails, in the State courts.

Accordingly, the State and City defendants' motions for judgment on the pleadings are granted.

Settle order on notice.

Dated: New York, N.Y.
December 2, 1974.

DUDLEY B. BONSAL
U. S. D. J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS and STANLEY WEINREB, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

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NOTICE OF SETTLEMENT

73 Civ. 2276 (DBB)

SIRS:

PLEASE TAKE NOTICE that the within order will be presented for settlement and signature to the Hon. Dudley B. Bonsal, United States District Judge at the office of the Clerk, Room 601, United States Courthouse, Foley Square, Borough of Manhattan, State of New York, on the eighth day of January, 1975 at 10:30

o'clock in the forenoon, or as soon thereafter as counsel can be heard.

Dated: New York, New York
December 23, 1974

Yours, etc.,

ADRIAN P. BURKE
Corporation Counsel of the
City of New York
Attorney for Municipal Defendants

By _____
David W. Fisher
Assistant Corporation Counsel
Municipal Building
New York, New York 10007
Tel. 566-4467

TO: ROTHBLATT, ROTHBLATT,
SEIJAS & PESKIN, ESQS.
232 West End Avenue
New York, New York 10023
Attorneys for Plaintiffs
By Henry Rothblatt, Esq.

HON. LOUIS J. LEFKOWITZ
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Attorney for State Defendants
David Spiegal, Esq.
Assistant Attorney-General, of counsel

HON. PAUL J. CURRAN
United States Attorney for the Southern
District of New York
Attorney for Defendants Weinberger and
Department of Health, Education and
Welfare
Gregory J. Potter, Esq.
Assistant United States Attorney, of counsel

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS and STANLEY WEINREB, on behalf of themselves and all other persons similarly situated,

Plaintiffs,

-against-

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration, HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America and the Department of Health, Education and Welfare of the United States of America,

Defendants.

73 Civ. 2276 (DBB)

ORDER

The City defendants, JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and

the Health Services Administration, by their attorney, Adrian P. Burke, Corporation Counsel of the City of New York (David W. Fisher, of counsel), and the State defendants HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; by their attorney, Louis J. Lefkowitz, Attorney General of the State of New York (David Spiegal, of counsel), having moved for judgment on the pleadings, or in the alternative, for summary judgment, having come on for a hearing before the Court on October 7, 1974, before the Hon. Dudley B. Bonsel, United States District Judge, presiding, and the Court having considered the motions and thereafter having rendered its opinion on December 2, 1974, it is hereby

ORDERED, that the State and City defendants' motions for judgment on the pleadings are granted, and it is further

ORDERED, ADJUDGED and DECREED, that the complaint herein be and the same is hereby dismissed.

Dated: New York, New York
December 23, 1974

_____
U. S. D. J.

AMENDED NOTICE OF APPEAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

---

FRIEDLANDER, et al.,

Plaintiffs,

-against-

CIMINO, et al.,

Defendants.

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AMENDED NOTICE OF APPEAL
73 Civ. 2276 (D.B.B.)

PLEASE TAKE NOTICE that the plaintiffs hereby appeal to the United States Court of Appeals for the Second Circuit from the order of Hon. Dudley B. Bonsal, United States District Judge, dated January 10, 1975 dismissing the action herein against the state and city defendants. This notice amends the premature notice previously filed.

DATED: New York, New York
January 20, 1975

Yours, etc.

ROTHBLATT, ROTHBLATT,
SEIJAS & PESKIN

by /s/
Attorneys for Plaintiffs
232 West End Avenue
New York, New York 10023
(212) 787-7001

TO: Hon. Paul Curran
United States Attorney
United States Courthouse
Foley Square
New York, New York

Hon. Louis Lefkowitz
Attorney General
State of New York
2 World Trade Center
New York, New York

Bernard Richland, Esq.
Corporation Counsel
Municipal Building
New York, New York

Received 1 copies of the within
Appendix
this 21 day of March, 1975.

COPY OF WITHIN PAPER RECEIVED
DEPARTMENT OF
MAR 21 1975
NEW YORK CITY OFFICE
ATTORNEY GENERAL

Sign _____

For: Hon Louis J. Lefkowitz Esq(s). Louis J. Lefkowitz

Att'ys for Appellee

Received 1 copies of the within
Appendix
this 21 day of March, 1975.

Sign _____

For: W Bernard Richland Esq(s).

Att'ys for Appellee

COPY RECEIVED
MAR 21 1975
PAUL J. CURRAN
U.S. ATTORNEY
S.D. DIST. OF N.Y.

Paul J. Curran
COPY RECEIVED
March 21, 1975
UNITED STATES ATTO

Received 1 copies of the within
Appendix
this 21 day of March, 1975.

Sign _____

For: Hon Paul Curran Esq(s).

Att'ys for Appellee